

Bayer CropScience



Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S4900
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

August 17, 2011

Attention: Tony Kish
Product Manager Team 22

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
RTP, NC 27709
Phone: (919) 549-2000

Subject: Proline 480 SC Fungicide, EPA Reg. No. 264-825
Prothioconazole Petition for Foliar Tolerances to Support Seed Treatment Use on
Cereal Grains Except Sorghum and Rice

Dear Mr. Kish:

Bayer CropScience is submitting the enclosed petition proposing that tolerances already established to cover foliar uses of the fungicide prothioconazole, 2-(2-(1-Chlorocyclopropyl)-3-(2-chlorophenyl-2-hydroxypropyl)-1,2-dihydro-3H-1,2,4-triazol-e-3-thione, on the cereal grain groups 15 and 16, except sorghum and rice, also cover seed treatment use.

With this petition we are also submitting an application to add seed treatment uses to our current Proline 480 SC Fungicide label.

Based on the revised fee schedule published in 75FR48672, we have determined that the proper fee for this PRIA R273 submission is \$137,262 (3 X \$45,754) based on the representative crops field corn, sweet corn, and wheat. In a March 28, 2011 e-mail from the Agency's John Jamula, Bayer CropScience was informed of \$71,512 in unused PRIA payments in the following payment IDs: 00713753, 3100016136, 3100036960, 3100038972, 3100054148, 3100058530, and 3100060745 (see enclosed John Jamula 3/28/2011 e-mail). Bayer CropScience would like to use these unused payments in partial payment of the PRIA fee for this submission. A check for the remaining fee, \$65,750 (\$137,262 - \$71,512), was sent to the Agency's St. Louis fee for service lockbox. A photocopy of the check is enclosed.



M-412073-01-1

Changes to 40 CFR § 158 made immunotoxicity (OPPTS Guideline 870.7800) and acute and subchronic neurotoxicity (OPPTS Guideline 870.6200) data a requirement for applications submitted after December 26, 2009. Bayer CropScience has acute and subchronic neurotoxicity data on file with the Agency under MRIDs 46246416 and 46246417. On March 11, 2010, Bayer CropScience submitted a waiver request for the immunotoxicity requirement based on additional supplementary data and the results of a comprehensive battery of immunotoxicity investigations performed in the subchronic toxicity study of prothioconazole in rats (MRIDs 48020401 through 48020410). Our waiver request was accepted in the Agency's September 14, 2010 HED memorandum.

If you have any questions or need additional information, please contact me by phone at (919) 549-2631 or by e-mail at mel.tolliver@bayer.com.

Sincerely,

Melvin K. Tolliver

Melvin K. Tolliver
Registration Product Manager, Fungicides

Enclosures:

1. Prothioconazole petition
2. Photocopy of PRIA R273 fee check for \$65,750 sent to EPA lockbox.
3. Copy of John Jamula 3/28/2011 e-mail
4. Draft labeling dated 06/17/2011 (clean and annotated copies)
5. Application (8570-1 Form) to add seed treatment uses to Proline 480 SC Fungicide label.
6. Certification with Respect to Citation of Data (8570-34 Form)
7. Data Matrices for Proline 480 SC Fungicide
8. Bayer CropScience Report Nos. MEJAY007-1, RA-2567/07, RA-2568/07, RA-2620/06, RA-2621/06